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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,371	10/12/2000	Matthew Cotten	0652.2150001/EKS/PAJ	5877

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
Attorneys at Law
Suite 600
1100 New York Avenue, N.W.
Washington, DC 20005-3934

EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	11

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/688,371	Applicant(s) COTTEN ET AL.	
	Examiner Shanon A. Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to a recombinant CELO virus or CELO virus DNA, classified in class 536, subclass 23.5.

II. Claims 17, 23, 26-29, drawn to a method of making a recombinant CELO virus in a host animal, classified in class 435, subclass 455.

III. Claims 18-22, drawn to a method of making a recombinant CELO virus in a cell, classified in class 435, subclass 91.1.

VI. Claim 24, drawn to a method of making a recombinant CELO virus in an animal, classified in class 435, subclass ~~356~~ 326.

V. Claims 30-33, drawn to a vaccine against infectious disease, classified in class 424, subclass 184.1.

VI. Claim 34, drawn to a CELO virus to make a tumor vaccine, classified in class 424, subclass 277.1.

VII. Claims 35-40, drawn to a method of making a protein of interest, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the

instant case the recombinant CELO virus or CELO DNA of group I can be made by at least three materially different processes outlined in groups II-IV.

Inventions II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions employ different method steps and materials to make the recombinant viruses. Group II requires amplification in any host animal, while group IV is limited to amplification in avian embryos. Groups II and IV are also distinct from one another because group VI requires additional steps and processing *in vitro*. Group III does not require a host animal, which is distinct from groups II and IV and requires additional steps from not required in group II.

Groups V and VI are patentably distinct from one another because group V requires that the components ameliorate infection and the composition of group VI indirectly directed against tumors, which are not necessarily caused by infectious agents. Also, the compositions are used to accomplish two entirely different goals. The composition of group V is directed to treating a preventing infectious disease, while the composition of group VI is used to make a tumor vaccine, which does not relate to ameliorating tumors.

The composition of group I is unrelated to the compositions of groups V and VI because the group I composition can be used in a multitude of distinct and unrelated purposes, such as making a tumor vaccine, making more recombinant CELO viruses, making a protein of interest, and making a tumor vaccine. Groups V and VI are limited for their own specific uses. Groups

II-VI are unrelated to groups V and VI because groups II-IV are drawn to distinct method steps for producing products, which are not directed to treatment.

Group VII is drawn to make a protein, which is distinctly different from methods for making recombinant CELO viruses in groups II-IV. Each group requires different method steps and require different ingredients to perform the method steps. The virus of group I is distinct from the method of group VII because the group I does not comprise any method steps and the CELO virus or CELO DNA of group I is structurally and functionally different from the protein generated by the method of group VII. In addition, group VII is distinct from groups V and VI because the product made by group VII does not have the intended use of preventing infectious disease or making tumor vaccines and is also functionally and structurally distinct from the materials in the vaccine and the materials used to make a vaccine.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
December 14, 2001

James C. Housel
JAMES HOUSEL 12/17/01
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600